UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Elizabeth Kahn, 16-17039	)	

ORDER AND REASONS

Before the Court is Plaintiff's Motion to Strike the Untimely Report of Ellen Chang, ScD (Doc. 12582). The Court held oral argument on the Motion on July 9, 2021. For the following reasons, the Motion is **DENIED**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second trial is set for August 23, 2021.[2]

Plaintiff Elizabeth Kahn, the second bellwether plaintiff, originally planned to call Dr. David Kessler as her regulatory expert at trial. Plaintiff has since learned, however, that Dr. Kessler is unavailable, and she has now

[1] Docetaxel is the generic version of Taxotere.
[2] The second trial was continued due to the COVID-19 pandemic.

designated Dr. David Ross and Dr. Laura Plunkett to provide regulatory opinions. To rebut the new opinions of these experts, Sanofi has offered supplemental opinions from their expert Dr. Ellen Chang. In the instant Motion, Plaintiff seeks to exclude Dr. Chang's supplemental expert report. Sanofi opposes the Motion.

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> > (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> >
> > (b) the testimony is based on sufficient facts or data;
> >
> > (c) the testimony is the product of reliable principles and methods; and
> >
> > (d) the expert has reliably applied the principles and methods to the facts of the case.[3]

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*[4] and *Kumho Tire Co. v. Carmichael*.[5] The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.[6] After defining the permissible scope of the expert's testimony,

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[3] FED. R. EVID. 702.
[4] 509 U.S. 579 (1993).
[5] 526 U.S. 137 (1999).
[6] Wagoner v. Exxon Mobil Corp., 813 F. Supp. 2d 771, 799 (E.D. La. 2011). *See also* Wilson v. Woods, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").

a court next assesses whether the opinions are reliable and relevant.[7] As the "gatekeeper" of expert testimony, the trial court enjoys broad discretion in determining admissibility.[8]

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert's testimony is valid.[9] The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.[10] Courts should exclude testimony based merely on subjective belief or unsupported speculation.[11] Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.[12] "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."[13] After assessing reliability, a court evaluates relevance.[14] In doing so, a court must determine whether the expert's reasoning or methodology "fits" the facts of the case and will thereby assist the trier of fact in understanding the evidence.[15]

Federal Rule of Evidence 703 further provides that an expert may offer opinions based on otherwise inadmissible facts or data but only if (1) they are of the kind reasonably relied upon by experts in the particular field; and (2) the testimony's probative value substantially outweighs its prejudicial effect.[16]

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[7] *See* United States v. Valencia, 600 F.3d 389, 424 (5th Cir. 2010). *See also* Wellogix, Inc. v. Accenture, L.L.P., 716 F.3d 867, 881–82 (5th Cir. 2013).
[8] *Wellogix*, 716 F.3d at 881.
[9] *See Daubert*, 509 U.S. at 592–93.
[10] *See* Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998).
[11] *See Daubert*, 509 U.S. at 590.
[12] *See id.* at 596.
[13] *Id.*
[14] Burst v. Shell Oil Co., 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).
[15] *Id.*
[16] FED. R. EVID. 703.

LAW AND ANALYSIS

Plaintiff argues that Dr. Chang's supplemental report does not contain any new regulatory opinions. Plaintiff argues that the report instead repeats challenges that Sanofi made regarding Plaintiff's expert biostatistician, Dr. David Madigan. According to Plaintiff, then, the opinions in Dr. Chang's supplemental report are untimely and should have been included in her original report. In response, Sanofi emphasizes that in their new labeling opinions, Dr. Ross and Dr. Plunkett rely heavily on Dr. Madigan's work, rendering Dr. Chang's supplemental opinions appropriate and timely.

After reviewing the supplemental report of Dr. Chang, the Court finds that the report is an appropriate rebuttal to the opinions of Dr. Ross and Dr. Plunkett. At the start of her report, Dr. Chang notes that Dr. Ross and Dr. Plunkett expressly rely on the work of Dr. Madigan.[17] Specifically, they rely on Dr. Madigan's analysis of the FDA's Adverse Event Reporting System (the "FAERS" database).[18] In his work, Dr. Madigan searched the FAERS database and, per Dr. Chang, "identified six observed reports that he classified as irreversible alopecia with docetaxel treatment as of the first quarter of 2008."[19]

Notably, this Court has previously rejected Sanofi's argument that for Dr. Madigan's FAERS analysis to be reliable, he needed to conduct both a "signal identification" and "signal evaluation."[20] In other words, Sanofi averred that Dr. Madigan should have individually assessed the reports he retrieved to ensure that each one related to permanent alopecia. The Court ruled, however, that Dr. Madigan, being a statistician, appropriately focused on

[17] Doc. 12582-2 at 2.
[18] *Id.*
[19] *Id.* at 3.
[20] Doc. 12098 at 13–14.

signal identification. A signal evaluation would involve an epidemiologic assessment, which falls outside the realm of Dr. Madigan's expertise.

Now, Drs. Ross and Plunkett rely on Dr. Madigan's signal identification to support their opinions. Dr. Ross, for example, in his assessment of "whether there is 'some basis to believe there is a causal relationship between' Taxotere and [permanent chemotherapy-induced alopecia]," pointed to Dr. Madigan's analysis of the FAERS database.[21] Dr. Ross, however, testified that he did not individually evaluate the reports that Dr. Madigan retrieved.[22]

To rebut Drs. Ross and Plunkett, Dr. Chang evaluated the reports that Dr. Madigan identified, and Dr. Chang opined that "these reports do not pertain to permanent or irreversible alopecia that persisted for at least six months."[23] She concludes that the reports "provide no evidence to support a causal effect of docetaxel on permanent or irreversible alopecia."[24] The Court sees this as an appropriate response to the work of Drs. Ross and Plunkett. The Court, therefore, rejects the notion set forth by Plaintiff that Dr. Chang is presenting opinions that should have been included in her original report.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Strike the Untimely Report of Ellen Chang, ScD (Doc. 12582) is **DENIED**.

New Orleans, Louisiana, this 10th day of July, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

[21] Doc. 12582-9 at 23, 29 (quoting regulations relating to drug labeling).
[22] Doc. 12738-3 at 3.
[23] Doc. 12582-2 at 8.
[24] *Id.*